NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MYLAN INC., et al.,	:	
Plaintiffs,	:	Civil Action No. 10-04809 (JAP)
v.	:	**OPINION**
SMITHKLINE BEECHAM CORPORATION, et al.,	:	
Defendant,	:	

Mylan Inc. and Mylan Pharmaceuticals Inc. (together, "Plaintiffs") bring this action alleging breach of contract against SmithKline Beecham Corporation, doing business as GlaxoSmithKline, SmithKline Beecham P.L.C. and SB Pharmco Puerto Rico Inc. (collectively, "GSK") and alleging inducement to breach contract and tortious interference against Apotex, Inc. and Apotex Corporation (together, "Apotex", and together with GSK, "Defendants"). Presently before the Court is a motion by Plaintiffs for a preliminary injunction. Oral argument was held October 18, 2010. For the reasons below and stated on the record of the proceedings, Plaintiffs' motion for a preliminary injunction is denied.

I. Background

GSK markets and sells Paxil CR, which is the brand name for paroxetine hydrochloride extended-release oral tablets in strengths of 12.5 mg, 25 mg and 37.5 mg. In June 2007, GSK filed a lawsuit against Plaintiffs in connection with Plaintiff's filing of an Abbreviated New Drug

Application relating to generic versions of Paxil CR. Following settlement negotiations in that litigation, GSK and Plaintiffs entered into the Patent License and Settlement Agreement, dated August 10, 2007 (the "Settlement Agreement"). GSK then submitted the Settlement Agreement to the Federal Trade Commission (the "FTC") for review. (Declaration of Kathleen W. Bradish ("Bradish Decl.") ¶¶ 2-3.) Upon review of the Settlement Agreement, the FTC stated that it intended to investigate the indefinite restrictions that the Settlement Agreement placed on GSK with respect to launching an authorized generic. (Bradish Decl. ¶ 4.) The FTC indicated that it was concerned about the effect that this restriction would have on competition for generic versions of Paxil CR and wanted to ensure that the restriction was not an illegal agreement not to compete with Plaintiffs. (Bradish Decl. ¶ 4.) In response, GSK and Plaintiffs re-negotiated certain terms of the Settlement Agreement to address the FTC's concerns and the parties subsequently entered into the Second Amendment to Patent License and Settlement Agreement, dated September 27, 2007 (the "Amended Settlement Agreement"). (Bradish Decl. ¶ 6.) The Amended Settlement Agreement provides that the patent licenses therein "shall be exclusive (even as to GSK) in favor of [Plaintiffs] for all Generic Paroxetine Products" except that "GSK or its Affiliate may commence marketing and selling generic paroxetine hydrochloride controlled or modified release products pursuant to its Paxil CR NDA at the end of the second year after [Plaintiff] launches its Generic Paroxetine Products" (the "Exception").

On September 17, 2010, Plaintiffs discovered that Apotex was offering or planning to offer for sale all three strengths of paroxetine extended-release tabs as authorized generics under GSK's New Drug Application ("NDA"). (Declaration of Harry A. Korman ¶ 10.) In fact, GSK and Apotex had entered into a Supply and Distribution Agreement, dated July 1, 2010 (the

"Supply and Distribution Agreement"), under which GSK agreed to sell an authorized generic of Paxil CR ("AG Paroxetine CR") to Apotex, which then had the right to distribute the product.

Plaintiffs filed this action on September 20, 2010, alleging breach of the Settlement Agreement against GSK and alleging inducement to breach the Settlement Agreement and tortious interference with the Settlement Agreement against Apotex. On that same day, Plaintiffs filed a motion for preliminary injunction and the Court issued an Order to Show Cause with temporary restraints, pending full briefing and oral argument on the motion for preliminary injunction.

II. Legal Standard and Analysis

Plaintiffs seek a preliminary injunction enjoining GSK from permitting Apotex to market and sell or otherwise launch generic paroxetine extended-release products pursuant to GSK's NDA. In evaluating a motion for preliminary injunctive relief, a court must consider whether: "'(1) the plaintiff is likely to succeed on the merits; (2) denial will result in irreparable harm to the plaintiff; (3) granting the injunction will not result in irreparable harm to the defendant; and (4) granting the injunction is in the public interest."' *NutraSweet Co. v. Vit-Mar Enterprises, Inc.*, 176 F.3d 151, 153 (3d Cir.1999) (quoting *Maldonado v. Houstoun*, 157 F.3d 179, 184 (3d Cir.1998)).

A preliminary injunction "should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997). Preliminary injunctive relief is an "extraordinary and drastic remedy", *id.*, which "should issue only if the plaintiff produces evidence sufficient to convince the district court that all four factors favor preliminary relief." *American Tel. and Tel. Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir.1994). "The burden lies with the plaintiff to establish every element

in its favor, or the grant of a preliminary injunction is inappropriate." *P.C. Yonkers, Inc. v. Celebrations the Party and Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005).

A. Likelihood of Success on the Merits

The Court finds that Plaintiffs have not made a clear showing that they are likely to succeed on the merits. The parties agree that the two year exclusivity period identified in the Exception has ended, meaning that GSK (or an affiliate thereof) is entitled to commence marketing and selling AG Paroxetine CR. The parties also agree that Apotex does come within the definition of "Affiliate" under the Settlement Agreement. Thus, the question before the Court is whether, as Defendants contend, GSK is entitled to sell AG Paroxetine CR to Apotex through the Supply and Distribution Agreement or whether, as Plaintiffs argue, it must sell AG Paroxetine CR by some other method.

Under New Jersey law, "[w]hen the terms of [a] . . . contract are clear, it is the function of a court to enforce it as written and not to make a better contract for either of the parties." *Kampf v. Franklin Life Ins. Co.*, 33 N.J. 36, 43, 161 A.2d 717, 720 (N.J. 1960). When a court is tasked with determining the meaning of an agreement, "the terms of the contract must be given their 'plain and ordinary meaning.'" *Kaufman v. Provident Life and Cas. Ins. Co.*, 828 F. Supp. 275, 282 (D.N.J. 1992).

Plaintiffs argue that the plain language of the Exception permits only GSK (or an Affiliate thereof) to market and sell AG Paroxetine CR and, further, that GSK (or an Affiliate thereof) must both market and sell the AG Paroxetine CR to fall within the Exception. Plaintiffs argue that GSK is only selling (and not marketing) the AG Paroxetine CR to Apotex and that GSK (or an Affiliate thereof) must engage in both selling and marketing activities for the Exception to be triggered.

On the other hand, Defendants argue that the plain language of the Exception allows GSK to begin selling an AG Paroxetine CR two years after Mylan launched its generic Paxil CR. They claim that under the Supply and Distribution Agreement, GSK will sell the finished form of AG Paroxetine CR to Apotex, which is exactly the scenario that the Exception was drafted to provide for.

"In the quest for the common intention of the parties . . . the court must consider the relations of the parties, the attendant circumstances, and the objects they were trying to attain." *Karl's Sales and Service, Inc. v. Gimbel Bros., Inc.*, 249 N.J. Super. 487, 492, 592 A.2d 647, 650 (App. Div. 1991) (citations omitted). "An agreement must be construed in the context of the circumstances under which it was entered into and it must be accorded a rational meaning in keeping with the express general purpose." *Id.* (citations omitted).

Considering the context of the circumstances under which the Amended Settlement Agreement was entered into, the Court finds that Plaintiffs have not made a clear showing that they are likely to succeed on the merits. The Amended Settlement Agreement was entered into to address the FTC's concerns with respect to competition in the market for generic versions of Paxil CR. Plaintiffs bargained for two year period of exclusivity. Given that the two year period of exclusivity has ended, the Court finds that GSK's selling of AG Paroxetine CR to Apotex, which will then further distribute the AG Paroxetine CR into the market, is in keeping with the common intention of the parties and the general purpose of the Amended Settlement Agreement.

This is a case of contract interpretation where both Plaintiffs and Defendants make convincing and plausible arguments with respect to the meaning of the Exception. Plaintiffs have not make a clear showing that their reading of the Exception is more convincing than

Defendants' or that they are likely to win on the merits and, as such, the Court is unable to grant the drastic remedy of a preliminary injunction.

B. Irreparable Harm

Continuing with the preliminary injunction analysis, the Court must next consider whether "denial will result in irreparable harm to the plaintiff" and whether "granting the injunction will not result in irreparable harm to the defendant." *NutraSweet*, 176 F.3d at 153 (citations omitted). Plaintiffs principally argue that GSK and Apotex's conduct will likely cause Mylan to lose market share and erode the price of the generic product and, further, that once the other generic product enters the market, the market will not go back to its former condition. Indeed, courts have found that irreversible market effects can constitute irreparable harm. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008); *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578, 596 (3d Cir. 2002).

Defendants argue that, since GSK (or an affiliate thereof) has the right to commence marketing and selling AG Paroxetine CR under the Exception, Plaintiffs are merely complaining about a harm that is a result of legitimate competition in the market for generic versions of Paxil CR. GSK points to case law stating that, to the extent that the harm about which Plaintiffs complain is self inflicted, Plaintiffs cannot show irreparable harm under the preliminary injunction. *See Caplan v. Fellheimer Eichen Braverman & Kaskey*, 68 F.3d 828, 839 (3d Cir. 1995); *Borough of Palmyra, Bd. of Educ. v. F.C. Through R.C.*, 2 F.Supp.2d 637, 644 (D.N.J. 1998). The Court finds that at least some of the harm that may be suffered by Plaintiff from irreversible market effects will be the result of competition in the market that Plaintiff expected

or should have expected to occur, given that the two year period of exclusivity under the Exception has ended.

The Court also notes that the general rule is that "[t]he irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot be adequately compensated after the fact by monetary damages." *Adams v. Freedom Forge Corp.*, 204 F.3d 475 (3d Cir.2000); see *Frank's GMC Truck Center, Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir.1988) (noting that suffering "substantial lost profits" is "compensable by money damages" and does not constitute irreparable injury). This is a contract dispute that can be litigated to a final determination against Defendants who are capable of withstanding a judgment for damages. Should Plaintiffs prevail at trial on their breach of contract action against GSK and tort action against Apotex, they can be adequately and sufficiently compensated by GSK and Apotex for any losses incurred.

The Court finds that Plaintiff has not made a clear showing that the irreversible market effects that will cause the irreparable harm to Plaintiff were not the result of legitimate market competition that Plaintiffs should have expected based on the end of the two year exclusivity period in the Exception. In addition, the Court is of the opinion that, to the extent that Plaintiff is able to show that some of the harm caused by the irreversible market effects was not the result of legitimate competition, such harm can be adequately compensated by monetary damages.

C. Public Interest

The final determination with respect to whether a party is entitled to preliminary injunction is whether "granting the injunction is in the public interest."' *NutraSweet*, 176 F.3d at 153. Although Plaintiffs correctly argue that the public has a strong interest in the enforcement of valid contracts, s*ee Ride the Ducks of Philadelphia, LLC v. Duck Boat Tours, Inc.*, 138 Fed.

Appx. 431, 434-435 (3d Cir. 2005); *Arch Personal Care Products, L.P. v. Malmstrom*, 90 Fed. Appx. 17, 20-22 (3d Cir. 2003), Defendants counter that general proposition and argue that the public has a strong interest in allowing GSK to sell AG Paroxetine CR to Apotex for further distribution into the market. The Court finds that GSK and Apotex's actions are in line with the legislative intent of the Hatch-Waxman Act, i.e. to foster competition in the market, resulting in reduced prices of beneficial drugs. Therefore, the Court finds that Plaintiffs have not made a clear showing that granting the preliminary injunction is in the public interest.

III. Conclusion

For the reasons above, Plaintiffs' motion for a preliminary injunction is denied. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: October 20, 2010